

Appl. No. 10/764,215
Docket No. P-142M
Amdt. Dated March 4, 2011
Reply to Office Action mailed on October 7, 2010
Customer No. 27752

REMARKS

Claim Status

Claims 1-4 and 6-17 are pending in the present application. Claims 10–17 were previously withdrawn as a result of an earlier restriction requirement.

With this Response, independent claim 1 has been amended to more clearly define the claimed subject matter. No new matter has been added. Consequently, entry of this amendment is respectfully requested.

Rejection Under 35 USC §103(a) Over Hayek (U.S. 6,133,323)

Claims 1, 2, 4, and 6-9 have been rejected under 35 USC §103(a) as being unpatentable over Hayek (U.S. 6,133,323). Applicants respectfully traverse.

In order for a case of obviousness to be established, in general, three criteria must be met. First, some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings must exist. USPTO Examination Guidelines for Determining Obviousness in View of *KSR Int'l. Co., v. Teleflex, Inc.*, No. 04-1350 (US, Apr. 30, 2007). Second, a reasonable expectation of success must exist. Finally, the prior art references must teach or suggest all of the claim limitations. MPEP § 2143.

Initially, Applicants respectfully submit that Hayek alone cannot support a *prima facie* case of obviousness because Hayek alone does not disclose, teach, or suggest a nutritionally balanced pet food composition that comprises astaxanthin. Hayek discloses providing a process for feeding a companion animal such as a dog or a cat a diet containing an effective amount of beta-carotene to enhance immune response and improve the overall health of the animal. See Column 1, lines 45-49. Hayek does mention in its Background that astaxanthin is a carotenoid. See Column 1, lines 16-19. Hayek states carotenoids are absorbed in varying degrees by different species and are known to play a role in modulating the immune system and enhancing the health of the species. See Column 1, lines 16-26. However, Hayek fails to disclose a pet food composition comprising astaxanthin. It states in this Background section that these

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carotenoids are absorbed by varying species. It does not state dogs or cats. It does not state incorporated astaxanthin into pet food compositions. It then continues its disclosure by stating its invention related to beta-carotene. It fails to disclose any pet food composition comprising astaxanthin. For that reason alone, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Moreover, as described on pages 6 and 7 of the present specification as filed, the inventors state,

“Until now, however, it has not been known whether companion animals (*e.g.*, dogs and cats) could absorb and utilize astaxanthin in effective pharmacological amounts, nor have the effects of any such absorption in cats or dogs been determined. In studies performed by the inventors, domestic dogs and cats which are fed astaxanthin show significant uptake by the blood and by all sub-cellular organelles of blood leukocytes. The present invention, therefore, provides compositions and methods useful for administering a companion animal a composition which contains astaxanthin as an ingredient or a food additive in an amount sufficient to provide, for example, from about 0.001 mg to about 40 mg, daily, of astaxanthin. Such a diet provides sufficient astaxanthin to be absorbed by the animal and supplied to the blood, *e.g.*, plasma, blood leukocytes, in the animal. The inventors have discovered that both domestic dogs and cats are able to absorb dietary astaxanthin. Furthermore, the inventors have discovered that circulating astaxanthin is significantly absorbed by blood leukocytes and is associated with high-density lipoprotein (HDL) in such animals. They have also discovered that astaxanthin is also distributed in the various sub-cellular organelles. Such absorption of astaxanthin into the various organelles of leukocytes is believed to (1) protect these cells from oxygen free radical attack and/or (2) directly regulate nuclear events. Thus, feeding companion animals such as dogs and cats a composition containing effective amounts of astaxanthin provides astaxanthin at important cellular sites in the body

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tissues of the animal that results in an up-regulation of immune function and improved health in these animals."

Therefore, based on this excerpt from the present specification, it would not have been obvious to include astaxanthin in a pet food composition since it was known whether companion animals could absorb and utilize astaxanthin in effective pharmacological amounts, nor were the effects of any such absorption in cats or dogs determined. Thus, such a modification to Hayek to include astaxanthin would not have been obvious.

Additionally, nothing is present in Hayek, nor has evidence or a convincing line of reasoning been presented, that suggests the desirability of modifying Hayek in such a manner as to arrive at the claimed invention. MPEP § 2142 states that the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at 412, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). Thus, the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. Applicants respectfully aver that the Office Action has failed to establish a *prima facie* case of obviousness of Claim 1 and the dependent claims therefrom. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

Lastly, it is noted that the dependent claims recite specific amounts of astaxanthin in the composition. These specific amounts are not disclosed, suggested, or taught in Hayek. Accordingly, these dependent claims should be considered for patentability on their own, and Applicants submit that the rejection of these claims should be withdrawn for that reason as well.

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CONCLUSION

This Response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied reference. In view of the foregoing, reconsideration of this application and allowance of the pending claims are respectfully requested.

Respectfully submitted,
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